

NOV 23 2004

Size 1 Triathlon™ CR Tibial Insert

Special 510(k) Premarket Notification

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Special 510(k) Summary

Proprietary Name: Size 1 Triathlon™ Cruciate Retaining (CR) Tibial Insert

Common Name: Modular Tibial Insert

Classification Name and Reference: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
21 CFR §888.3560

Proposed Regulatory Class: Class II

Device Product Code: 87 JWH

Predicate Proprietary Name: Triathlon™ CR Tibial Insert – Sizes 2-8

Predicate Regulatory Class: Class II

Predicate Product Code: 87 JWH

For Information contact: Denise Duchene
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
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Mahwah, New Jersey 07430
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Description/Technological Comparison

This premarket notification describes a smaller size of Triathlon™ Cruciate Retaining Tibial Insert. This smaller size insert is intended to be used with the size 1 Triathlon™ Primary Cemented Tibial Tray and the Triathlon™ CR Femoral component in primary or revision total knee arthroplasty. This size 1 tibial insert has smaller anterior-posterior and medio-lateral

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dimensions than the size 2 predicate.

Intended Use

The intended use of the size one Triathlon™ Cruciate Retaining Tibial Insert is the same as that of the predicate device described in premarket notification K040267 – it is intended for use with Triathlon™ Cruciate Retaining femoral components, Triathlon™ Primary Cemented Tibial Tray, and Triathlon™ and/or Duracon® patellar components in primary or revision cemented total knee arthroplasty. The cruciate retaining design is intended to accommodate the posterior cruciate ligament if it is present.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2004

Ms. Denise Duchene
Sr. Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K042883

Trade/Device Name: Size 1 Triathlon™ Cruciate Retaining (CR) Tibial Insert

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II

Product Code: JWH

Dated: October 15, 2004

Received: October 19, 2004

Dear Ms. Duchene:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

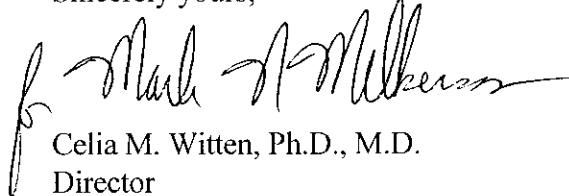
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042883

Device: Size 1 Triathlon™ CR Tibial Insert

The Triathlon™ CR Size 1 tibial inserts are intended to be used with the previously cleared Triathlon™ Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon™ CR Total Knee System is intended to accommodate the posterior cruciate ligament (PCL) if it is present. Specific indications and contraindications are listed below:

Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or, rheumatoid arthritis
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

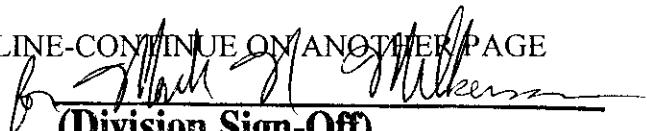
Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.

Obesity. An overweight or obese patient can produce loads on the prosthesis that can lead to failure of the fixation of the device or to failure of the device itself.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)


(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K042883